UNITED STATES DISTRICT COURT for the DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA

ex rel. [UNDER SEAL],

Plaintiffs,

v.

[UNDER SEAL],

Defendant.

Civ. Action No. _____

***QUI TAM* COMPLAINT**
FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)2
DEMAND FOR JURY TRIAL

UNITED STATES DISTRICT COURT for the DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA

ex rel. Sejal Patel

Plaintiffs,

v.

ASTRAZENECA PHARMACEUTICALS LP, JANSSEN PHARMA LLC, and NOVARTIS PHARMACEUTICALS CORPORATION,

Defendants.

Civ. Action No. _____

***QUI TAM* COMPLAINT FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)2**

DEMAND FOR JURY TRIAL

COMPLAINT

On behalf of the United States of America, the Relator files this *qui tam* Complaint against Defendants ASTRAZENECA PHARMACEUTICALS LP, JANSSEN PHARMA LLC, and NOVARTIS PHARMACEUTICALS CORPORATION, and alleges as follows:

INTRODUCTION

1. This is an action brought by Relator Sejal Patel to recover treble damages and civil penalties on behalf of the United States of America ("Government") arising from unlawful schemes by Defendants AstraZeneca Pharmaceuticals LP ("AstraZeneca"), Janssen Pharma LLC ("Janssen") and Novartis Pharmaceuticals Corporation ("Novartis")(collectively "Defendants").

2. The Defendants pay illegal inducements to beneficiaries of Medicare and other Government-funded health plans in the form of free trials of prescription medication which is illegal and leads to overutilization and waste of taxpayer funds.

3. The Office of Inspector General of the Department of Health and Human Services ("OIG") described this type of scheme as "seeding" where "a manufacturer might offer a drug for free or at a greatly reduced cost to induce a patient onto that drug and for the patient to obtain subsequent supplies that would be billed to Federal health care programs."

4. This is a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS") and of the Federal False Claims Act, 31 U.S.C. §§ 3729 t seq., as amended ("FCA").

PARTIES

5. Relator Sejal Patel is a pharmacist licensed by the States of New Jersey and New York.

6. She worked as a pharmacist for over ten years.

7. It was through her work as a pharmacist that the Relator became familiar with the regulatory prohibitions on pharmaceutical manufacturers providing free trials of prescription medications to beneficiaries of Medicare and other Government-funded health plans.

8. It was also through her work as a pharmacist that the Relator learned that the Defendants violated that prohibition by offering free trials to beneficiaries of Medicare and other Government-funded health plans.

9. AstraZeneca is a Delaware limited partnership.

10. Upon information and belief, AstraZeneca is the United States-based, wholly-owned subsidiary of the global drugmaker of the same name, headquartered in the United Kingdom.

11. AstraZeneca describes itself as a "global, science-led biopharmaceutical business."

12. It operates research and manufacturing facilities in three locations in the United States, namely the States of Delaware, Maryland and the Commonwealth of Massachusetts.

13. AstraZeneca manufactures and sells pharmaceutical products to patients across the United States, including beneficiaries of Medicare and other Government-funded health plans.

14. As further detailed below, these products include: Brilinta, Xigduo, Bydureon, Calquence, Farxiga, Kombiglyze, Lokelma, Symbicort and, Dulera.

15. Janssen is a Delaware limited liability company.

16. Upon information and belief, Janssen is the United States-based, wholly-owned subsidiary of the global drugmaker of the same name, headquartered in the Netherlands.

17. Janssen describes itself as "a leading pharmaceutical company in the United States."

18. Janssen is headquartered in Titusville, New Jersey.

19. Janssen manufactures and sells pharmaceutical products to patients across the United States, including beneficiaries of Medicare, Medicaid and other Government-funded health plans. As further detailed below, these products include Xarelto, Invokana and Invokamet.

20. Novartis is a Delaware corporation with headquarters at 1 Health Plaza, East Hanover, New Jersey.

21. Novartis is a global pharmaceutical company whose products are sold in 155 countries.

22. It manufactures and sells pharmaceutical products to patients across the United States, including beneficiaries of Medicare and other Government-funded health plans. As further detailed below, these products include the blood pressure medication Entresto.

JURISDICTION AND VENUE

23. Venue and jurisdiction are the same under the FCA. 31 U.S.C. § 3732. An action may be brought in any judicial district in which any defendant may be found or in which any proscribed act occurred. 31 U.S.C. § 3732(a). The United States District Court for the District of New Jersey has jurisdiction and venue for any Complaint brought in the matter because the Defendant is located in this district.

24. Relator is unaware that the allegations in this Complaint have been publicly disclosed. Further, to the extent that any of the information in this Complaint has been publicly disclosed, Relator's allegations in this Complaint are not based on such public disclosures.

25. Additionally, Relator is an original source of the information upon which the allegations are based because he has direct and independent knowledge of it.

Pursuant to 31 U.S.C. § 3730(b)(2), the Relator must provide the Government with a copy of the Complaint and/or a written disclosure of substantially all material evidence and material information in their possession contemporaneous with the filing of the Complaint. Relator has

complied with this provision by serving a pre-suit Disclosure Statement with attached exhibits upon Andrew Caffrey, Assistant United States Attorney for the District of New Jersey on or about December 20, 2021.

26. In further compliance with 31 U.S.C. §3730(b)(2), Relator shall, contemporaneously with the filing of this Complaint, serve copies of this Complaint upon the Assistant United States Attorney for the District of New Jersey and on the Honorable Merrick Garland, Attorney General of the United States.

27. In further compliance with 31 U.S.C. § 3730(b)(2), this Complaint is being filed *in camera* and will remain under seal for a period of at least sixty days and shall not be served on the Defendants until the Court so orders.

GOVERNING LAWS, REGULATIONS AND CODES OF CONDUCT

A. The False Claims Act

28. Originally enacted in 1863, Congress substantially amended the FCA in 1986. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud, against the United States. Further clarifying amendments were adopted in May 2009 and March 2010.

29. The FCA imposes liability upon any person who "knowingly presents, or causes to be presented [to the Government] a false or fraudulent claim for payment or approval;" or "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim;" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. 3729(a)(1)(A), (B), (G). Any person

found to violate these provisions is liable for a civil penalty of up to $11,000 for each such false or fraudulent claim, plus three times the amount of the damages sustained by the Government.

30. Significantly, the FCA imposes liability where the conduct is merely "in reckless disregard of the truth or falsity of the information" and further clarifies that "no proof of specific intent to defraud is required." 31 U.S.C. 3729(b)(1).

31. The FCA also broadly defines a "claim" as one that includes "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that — (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government — (i) provides or has provided any portion of the money or property requested or demanded; or (ii) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." 31 U.S.C. § 3729(b)(2)(A).

32. The FCA empowers private persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery.

33. In further compliance with 31 U.S.C. § 3730(b)(2), this Complaint is being filed *in camera* and will remain under seal for a period of at least sixty days and shall not be served on the Defendants until the Court so orders.

B. Federally Funded Health Insurance Programs

1. Medicare

34. Medicare is a federally-funded health insurance program for the elderly and persons with certain disabilities, providing both hospital insurance. Medicare Part A covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B covers medically necessary outpatient medical care including DMEPOS prescribed by a physician.

35. Medicare payments come from the Medicare Trust Fund, which is funded primarily by payroll deductions taken from the United States work force through mandatory Social Security deductions.

36. Medicare is generally administered by the Centers for Medicare and Medicaid Services ("CMS"), which is an agency of the Department of Health and Human Services ("HHS"). CMS establishes rules for the day-to-day administration of Medicare. CMS contracts with private companies to handle the day-to-day administration of Medicare.

37. CMS, through contractors, maintains and distributes fee schedules for the payment of physician services and medical equipment. These schedules specify the amounts payable for defined types of medical services and procedures and medical equipment.

2. Medicaid

38. Medicaid is a state and federal assistance program to provide payment of medical expenses for low-income patients. Medicaid was created in 1965 in Title XIX of the Social Security Act. Funding for Medicaid is shared between the federal government and state programs that choose to participate in Medicaid.

39. At all relevant times to this matter, applicable Medicaid regulations relating to coverage of claims by providers and physicians have been substantially similar in all material respects to the applicable Medicare provisions described above.

3. Tricare

40. TRICARE is a federal program which provides civilian health benefits for military personnel, military retirees, and their families. TRICARE is administered by the Department of Defense ("DOD") and funded by the Federal Government. *See* 32 C.F.R. 199.17.

41. At all relevant times to the matter, applicable TRICARE regulations relating to coverage of claims by providers and physicians have been substantially similar in all material respects to the applicable Medicare provisions described herein.

4. Federal Employees Health Benefit Plan ("FEHBP")

42. FEHBP provides health insurance coverage for nearly 8.7 million federal employees, retirees and their dependents. It is a collection of individual healthcare plans, including the Blue Cross and Blue Shield Association and the Government Employees Health Association.

43. At all relevant times to the matter, applicable FEHBP regulations relating to coverage of claims by providers and physicians have been substantially similar in all material respects to the applicable Medicare provisions described herein.

44. Medicare, Medicaid, TRICARE, FEHBP and other similar federally-funded programs are referred to collectively herein as "Government-funded health plans."

C. The Anti-Kickback Statute ("AKS")

45. The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for

the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program. §1128B(b).

46. The statute's prohibition also extends remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program. Id.

47. For purposes of the AKS, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Id.

48. The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program. *E.g., United States v. Nagelvoort,* 856 F.3d 1117 (7th Cir. 2017); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

49. Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to 10 years, or both.

50. Further, any claim for reimbursement made to a Federal health care program that "includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA.]" §1320(g).

51. The provision of free medications to patients, some of whom are beneficiaries of Government-funded health care programs, constitutes "remuneration" for purposes of the AKS as it may induce those patients to select the medication when reimbursable by a Government-funded health care program.

52. While the provision of free medications to patients violates the AKS and the FCA when the requisite intent is present recent advisory opinions published by HHS are instructive for understanding the Department's concern and ongoing policing of free drug arrangements as well as for understanding the peculiar features of these programs.

53. HHS explains that one of its primary concerns of free drug programs is with "problematic seeding." HHS-OIG Advisory Opinion 15-11.

54. These are arrangements where "a manufacturer might offer a drug for free or at a greatly reduced cost to induce a patient onto that drug and for the patient to obtain subsequent supplies that would be billed to Federal health care programs." Id.

55. HHS explained that while certain arrangements would likely constitute a violation of the AKS, HHS would not impose penalties where the free supply program was not marketed directly to patients.

56. HHS would permit circumstances where those patients would unlikely know about the free supply program at all unless and until their coverage determination was delayed and thus the program would give the patients no reason to favor that particular medication or to prevail upon their physician to prescribe it over any alternatives.

57. As detailed further below, the drugs and the free supply programs at issue in the present matter are marketed directly to patients which clearly violates HHS' regulations designed to prohibit circumstances where patients will favor those drugs when they are free and then continue to use them when they are covered by a Federal health program.

58. The OIG permitted arrangements that otherwise would constitute a violation of the AKS, where there was virtually no danger of "seeding" as the treatment was a "potentially curative" one-time treatment. Id.

59. In contrast, the defendants' drugs at issue in the present matter are palliative and not curative. They are designed to control and manage chronic conditions – conditions that would require the patient to stay on the drugs for the remainder of their lives.

60. Patients who obtain a free supply of the drugs will likely need to continue controlling and managing the condition for their foreseeable future.

61. To the extent that they are induced to select the defendants' drugs because of the initial free trial they will likely be induced to continue utilizing the drug once the trial is over and the drug is covered by a Federal health care program.

62. This is not only a violation of the AKS and FCA, but a textbook example of the sort of problematic seeding program prohibited by HHS.

COURSE OF CONDUCT

63. The Defendants pay inducements to beneficiaries of Medicare and other Government-funded health plans in the form of free trials of prescription medication.

64. This is unlawful under the AKS and the FCA because it induces the patients to utilize the medications when offered at little to no cost and then obtain subsequent supplies of the same medication that would be reimbursable by a Federal health care program.

65. As noted above, the OIG describes this sort of scheme as "seeding" in which the manufacturer "plants" the seeds of future demand for its product in the form of free samples to patients in the hopes that those seeds will later blossom into lucrative revenue.

66. The Defendants market these medications directly to the patients in the hopes that the patient will prevail upon their physicians for to fill a life-time prescription.

67. While direct-to-consumer marketing remains lawful in the United States, offering the consumer or patient something of value, such as a free-trial of the medication, is strictly prohibited.

68. Below are the specific medications manufactured, marketed and "seeded" as free trials by the Defendants to beneficiaries of Government-funded health plans.

A. ASTRAZENECA

69. Defendant AstraZeneca pays inducements to beneficiaries of Medicare and other Government-funded health plans in the form of free trials of prescription medication. These include, but are not limited to, the following:

- Brilinta is a blood thinner used to prevent heart attacks and strokes. AstraZeneca offers a free 30-day supply to all "Medicare Part D or Medicaid Patients." Patients prescribed Brilinta will likely need more than a 30-day supply as it treats a chronic condition. It is clear that AstraZeneca offers this 30-day free supply to induce the patients' business after the free supply runs out and the drug becomes reimbursable by Medicare or other Government-funded health plans.
- Xigduo is used to control high blood sugar in individuals with Type II diabetes. AstraZeneca offers a free 30-day supply to all "Medicaid, Medicare" patients. Patients prescribed Xigduo will likely need more than a 30-day supply as it treats a chronic condition. It is clear that AstraZeneca offers this 30-day free supply to induce the patients' business after the free supply runs out and the drug becomes reimbursable by Medicare or other Government-funded health plans.
- Bydureon, is used to control high blood sugar in individuals with Type II diabetes. AstraZeneca offers a free 28-day supply to all "Medicaid, Medicare" patients. Patients prescribed Bydureon will likely need more than a 28-day supply as it treats a chronic condition. It is clear that AstraZeneca offers this 28-day free supply to

induce the patients' business after the free supply runs out and the drug becomes reimbursable by Medicare or other Government-funded health plans.

- Calquence is used to treat individuals with chronic lymphocytic leukemia. AstraZeneca offers a free 30-day supply to all "Medicaid, Medicare" patients. Patients prescribed Calquence will likely need more than a 30-day supply as it treats a chronic condition. It is clear that AstraZeneca offers this 30-day free supply to induce the patients' business after the free supply runs out and the drug becomes reimbursable by Medicare or other Government-funded health plans.
- Farxiga Calquence is used to control high blood sugar in individuals with Type II diabetes. AstraZeneca offers a free 30-day supply to all "Medicaid, Medicare" patients. Patients prescribed Farxiga will likely need more than a 30-day supply as it treats a chronic condition. It is clear that AstraZeneca offers this 30-day free supply to induce the patients' business after the free supply runs out and the drug becomes reimbursable by Medicare or other Government-funded health plans.
- Kombiglyze, is used to control high blood sugar in individuals with Type II diabetes. AstraZeneca offered a limited free trial of Kombiglyze to beneficiaries of Government-funded health plans. Patients prescribed Kombiglyze needed the medication for longer than the length of the free trial as it treats a chronic condition. It is clear that AstraZeneca offered this free trial to induce the patients' business after the free supply ran out and the drug became reimbursable by Medicare or other Government-funded health plans.
- Lokelma is used to control high levels of potassium in the blood. AstraZeneca offered a limited free trial of Lokelma to beneficiaries of Government-funded

health plans. Patients prescribed Lokelma needed the medication for longer than the length of the free trial as it treats a chronic condition. It is clear that AstraZeneca offered this free trial to induce the patients' business after the free supply runs out and the drug became reimbursable by Medicare or other Government-funded health plans.

- Symbicort, is used to control and prevent symptoms caused by asthma or other chronic lung diseases. AstraZeneca offered a limited free trial of Symbicort to beneficiaries of Government-funded health plans. Patients prescribed Symbicort needed the medication for longer than the length of the free trial as it treats a chronic condition. It is clear that AstraZeneca offered this free trial to induce the patients' business after the free supply runs out and the drug became reimbursable by Medicare or other Government-funded health plans.
- Dulera is used to control symptoms of asthma such as wheezing. AstraZeneca offered a limited free trial of Dulera to beneficiaries of Government-funded health plans. Patients prescribed Dulera needed the medication for longer than the length of the free trial. It is clear that AstraZeneca offered this free trial to induce the patients' business after the free supply runs out and the drug became reimbursable by Medicare or other Government-funded health plans.

B. JANSSEN

70. Defendant Janssen pays inducements to beneficiaries of Medicare and other Government-funded health plans in the form of free trials of prescription medication. These include, but are not limited to, the following:

- Xarelto is used to treat and prevent deep venous thrombosis, a condition in which harmful blood clots form in vessels of the legs Janssen offers a free 30-day supply to Medicare Part D patients. Patients prescribed Xarelto will likely need more than a 30-day supply as it treats a chronic condition. It is clear that Janssen offers this 30-day free supply to induce the patients' business after the free supply runs out and the drug becomes reimbursable by Medicare or other Government-funded health plans.
- Invokana and Invokamet are used to control high blood sugar in individuals with Type II diabetes. Janssen offers a free 30-day supply to Medicare Part D patients. Patients prescribed Invokana or Invokamet will likely need more than a 30-day supply as it treats a chronic condition. It is clear that Janssen offers this 30-day free supply to induce the patients' business after the free supply runs out and the drug becomes reimbursable by Medicare or other Government-funded health plans.

C. NOVARTIS

71. Defendant Novartis pays inducements to beneficiaries of Medicare and other Government-funded health plans in the form of free trials of prescription medication. These include, but are not limited to, the following:

- Entresto is used to treat individuals with chronic heart failure to reduce the risk of death and hospitalization. Novartis offers a free 30-day supply to beneficiaries of Government-funded health plans. Patients prescribed Entresto will likely need more than a 30-day supply as it treats a chronic condition. It is clear that Novartis offers this 30-day free supply to induce the patients' business after the free supply

runs out and the drug becomes reimbursable by Medicare or other Government-funded health plans.

72. The free trials described above are designed by the Defendants to induce patients to utilize the above-referenced medications as they are offered at no cost with the expectation that those patients will continue to use the medications after the free trial expired and the medication becomes reimbursable by a Government-funded health plan.

73. For this reason, these free trials violate the AKS and the FCA.

DEFENDANTS' IMPROPER CONDUCT CAUSED SUBSTANTIAL DAMAGE TO THE GOVERNMENT

74. Defendants violated the AKS and the FCA by knowingly making false statements to obtain reimbursement from Government-funded health plans by paying illegal inducements to beneficiaries of Medicare and other Government-funded health plans in the form of free trials of prescription medications.

75. Through this conduct, Defendants ignored their patients' health care needs and damaged the Government significantly by causing millions of dollars in false or fraudulent claims for reimbursement.

CONCLUSION

76. Defendants caused the Government to incur substantial damages by presenting, making, using or causing to be presented, made or used thousands of False Claims to Government-funded health programs and private insurers in connection with its fraudulent schemes.

77. The False Claims resulted in remuneration unlawfully received by the Defendants.

78. More specifically, Defendants violated §(b)(2) of the AKS (42 U.S.C. § 1320a-7b(b)(2)) and numerous provisions of the FCA, including, but not limited to, the following: 31 U.S.C. §

3729(a)(1)(A); 31 U.S.C. § 3729(a)(1)(B); 31 U.S.C. § 3729(a)(1)(C); 31 U.S.C. § 3729(a)(1)(D); 31 U.S.C. § 3729(a)(1)(G).

79. In light of the foregoing, Defendants are liable to the United States for civil penalties and statutory damages.

80. The estimated damages to the United States caused by the false claims alleged herein are significant.

CLAIMS FOR RELIEF

COUNT I
False Claims Act: Presentation of False Claims
31 U.S.C. § 3729(a)(1)(A)

81. Relator repeats and incorporates by reference the allegations above as if fully contained herein.

82. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, Defendants have "knowingly present[ed], or cause[d] to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval" in violation of 31 U.S.C. § 3729(a)(1).

83. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $5,000 and as much as $11,000 for each such false or fraudulent claim submitted on or before November 2, 2015 and up to $21,563 for violations committed after November 2, 2015, plus three times the amount of the damages sustained by the Government for each and every violation of 31 U.S.C. § 3729 arising from Defendants' unlawful conduct as described herein. See 28 C.F.R. §§ 85.3(a)(9).

COUNT II
False Claims Act: Making or Using a False Record or Statement to Cause Claim to be Paid
31 U.S.C. § 3729(a)(1)(B)

84. Relator repeats and incorporates by reference the allegations above as if fully contained herein.

85. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, the Defendants have "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement – *i.e.*, the false certifications and representations made or caused to be made by the Defendants – to get a false or fraudulent claim paid or approved by the Government" in violation of 31 U.S.C. § 3729(a)(2).

86. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $5,000 and as much as $11,000 for each such false or fraudulent claim submitted on or before November 2, 2015 and up to $21,563 for violations committed after November 2, 2015, plus three times the amount of the damages sustained by the Government for each and every violation of 31 U.S.C. § 3729 arising from Defendants' unlawful conduct as described herein. See 28 C.F.R. §§ 85.3(a)(9).

COUNT III
False Claims Act: Conspiracy to Commit a Violation
31 U.S.C. § 3729(a)(1)(C)

87. Relator repeats and incorporates by reference the allegations above as if fully contained herein.

88. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, the Defendants and its agents have "conspire[d] to commit a violation of subparagraph (A), (B), (D)…or (G)" in violation of 31 U.S.C. §3729(a)(1)(C).

89. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $5,000 and as much as $11,000 for each such false or fraudulent claim submitted on or before November 2, 2015 and up to $21,563 for violations committed after November 2, 2015, plus three times the amount of the damages sustained by the Government for each and every violation of 31 U.S.C. § 3729 arising from Defendants' unlawful conduct as described herein. See 28 C.F.R. §§ 85.3(a)(9).

COUNT IV
False Claims Act: Knowingly Delivers Less Than All of Government's Property in Defendants' Possession
31 U.S.C. §3729(a)(1)(D)

90. Relator repeats and incorporates by reference the allegations above as if fully contained herein.

91. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, the Defendants "ha[d] possession, custody, or control of property or money used, or to be used, by the Government and knowingly deliver[ed], or cause[d] to be delivered, less than all of that money or property" in violation of 31 U.S.C. §3729(a)(1)(D).

92. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $5,000 and as much as $11,000 for each such false or fraudulent claim submitted on or before November 2, 2015 and up to $21,563 for violations committed after November 2, 2015,

plus three times the amount of the damages sustained by the Government for each and every violation of 31 U.S.C. § 3729 arising from Defendants' unlawful conduct as described herein. See 28 C.F.R. §§ 85.3(a)(9).

COUNT V
False Claims Act: Knowingly Conceals or Improperly Avoids an Obligation to Pay Money to the Government
31 U.S.C. §3729(a)(1)(G)

93. Relator repeats and incorporates by reference the allegations above as if fully contained herein.

94. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, each of the Defendants "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases and obligation to pay or transit money or property to the Government: in violation of 31 U.S.C. §3729(a)(1)(G).

95. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $5,000 and as much as $11,000 for each such false or fraudulent claim submitted on or before November 2, 2015 and up to $21,563 for violations committed after November 2, 2015, plus three times the amount of the damages sustained by the Government for each and every violation of 31 U.S.C. § 3729 arising from Defendants' unlawful conduct as described herein. See 28 C.F.R. §§ 85.3(a)(9).

COUNT VI
The Anti-Kickback Statute
42 U.S.C. §1320a-7b(b)(2)

96. Relator repeats and incorporates by reference the allegations above as if fully contained herein.

97. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, the Defendants solicit, receive, offer, or pay remuneration in exchange for referring patients to receive certain services that are paid for by Government-funded health plans.

98. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

PRAYERS FOR RELIEF

WHEREFORE, for each of these claims, the *Qui Tam* Plaintiff requests the following relief from each of the Defendants, jointly and severally:

a. Three times the amount of damages that the Government sustains because of the acts of Defendants;

b. A civil penalty of for each violation;

c. An award to the *Qui Tam* Plaintiff for collecting the civil penalties and damages;

d. Award of an amount for reasonable expenses necessarily incurred;

e. Award of the *Qui Tam* Plaintiff's reasonable attorneys' fees and costs;

f. Interest; and

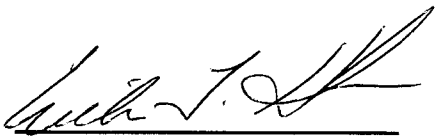
g. Such further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Relator hereby demands a trial by jury as to all issues.

March 3, 2022

Respectfully Submitted:



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ATTORNEYS FOR RELATOR